08/259,321

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EXAMINER	
JOHNSON, N	
ART UNIT	**PAPER NUMBER**
1806	19

DATE MAILED: 02/03/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 11/3/97 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~_____ days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-3, 5, 7-8, 14-21 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 5, 7-8, 14-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

1. Claims 1, 7, 14, 17 and 18 have been amended.

Claims 1-3, 5, 7-8, 14-15 and 17-21 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-3, 5, 7-8, 14-15, 17-21 under 35 U.S.C. § 112, first paragraph, as failing to provide complete evidence either that the claimed the hybridoma cell line ATCC No. HB 9892 is known and readily available to the public or complete evidence of the deposit of the biological materials is maintained. The applicant argues that declarations regarding the deposit of hybridoma cell line ATCC No. HB 9892 were filed in parent applications, issued patents 5.336.610 and 5,202,253 and are therefore public documents of the agreement by the depositor to maintain and make available the antibodies under the terms of the Budapest Treaty. This is not found persuasive. All such declarations must be of record in this case, citing the instant application number. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is also required.

4. The rejection of claims are 1 and 14 under 35 U.S.C. 112, first paragraph, as containing new subject matter which was not described in the specification is withdrawn in view of the amendments to the claims.

5. The rejection of claims 1-3, 5, 7-8, 14-15 and 17-21 are rejected under 35 U.S.C. § 112, first paragraph, is withdrawn in view of the amendments to the claims.

6. The rejection of claims 1-3, 5, 7-8, 14-15 and 17-21 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendments to the claims.

7. The rejection of claims 1-2, 5, 7-8, 14-15 and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,253 is maintained.

8. The rejection of claims 1-3, 5, 7-8, 14-15 and 17-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,202,253 in view of Morrison or Queen is maintained.

9. The rejection of claims 1-2, 5, 7-8 and 20 under 35 U.S.C. § 102(b) and (e) as being anticipated by U.S. Patent No. 5,202,253 or U.S. Patent No. 5,147,638 is maintained. The applicant argues that as the claimed antibody is expressed in bacterial cells, it will have a different glycosylation pattern that the antibody produced in a mammalian cell, and thus differs from the antibody disclosed U.S. Patent No. 5,202,253 or U.S. Patent No. 5,147,638. This is correct. However, the claimed antibody is either "expressed in bacterial cells or contains human amino acid sequence." The same 20 amino acids are used in both murine and human amino acid sequences. Thus, the disclosed murine antibody will contain, for example an alanine or a serine residue, as will the claimed antibody, "containing human amino acid sequence." Thus the disclosed antibody is the same as that claimed.

10. The rejection of claims 1-2, 5, 7-8 and 20 under 35 U.S.C. § 102(b) as being anticipated by D'Angelo et al. (J. Clin. Invest. 77) or Stearns et al. (J. Biol. Chem. 263) is maintained. As discussed in the paragraph above, both the disclosed antibody and the claimed antibodies "contain human amino acid sequence. Thus, the antibodies disclosed in D'Angelo or Stearns are the same as that claimed. The applicant argues that both the D'Angelo and Stearns references were overcome as applicable art in the prior prosecution of parent patent '638 and '253. This si not found persuasive. All relevant arguments and/or declarations must be of record in the instant application file to be duly considered.

11. The rejection of claims 1-3, 5, 7-8, 1415 and 17-21 under 35 U.S.C. § 103 as being unpatentable over any of U.S. Patent No. 5,202,253, U.S. Patent No. 5,147,638, D'Angelo et al. (J. Clin. Invest. 77) or Stearns et al. (J. Biol. Chem. 263) in view of Morrison or Queen is maintained. The applicant argues that the one of skill in the art would not have a reasonable expectation of success of obtaining the claimed antibodies by following the teachings of U.S. Patent No. 5,202,253, U.S. Patent No. 5,147,638, D'Angelo or Stearns in view of Morrison or Queen. This is not found persuasive.

The applicant argues that in the absence of a nucleotide sequence of the HPC-4 antibody, one of skill in the art can not have a reasonable expectation of success in making the claimed antibody; humanized HPC-4 or HPC-4 expressed in bacterial cells. This is not found persuasive. The level of skill in the art of sequencing immunoglobulin proteins, such as the HPC-4 protein (and thus deducing nucleotide sequences) and the art of cloning the genes encoding antibodies (from the hybridoma cell line secreting the HPC-4 antibody) was very sophisticated at the time of filing of the instant application. From the combined teachings of U.S. Patent No. 5,202,253, U.S. Patent No. 5,147,638, D'Angelo or Stearns in view of Morrison or Queen one of skill in the art has a reasonable expectation of success in obtaining the nucleotide sequence encoding the HPC-4 antibody and a reasonable expectation of success of making the claimed antibody proteins.

The applicant's arguments directed to the fact that the HPC-4 monoclonal antibody is a highly unusual antibody, impossible to duplicate are not persuasive. The HPC-4 monoclonal antibody (and implicitly, the hybridoma cell line that secretes this antibody) is available for use (as taught in U.S. Patent No. 5,202,253, U.S. Patent No. 5,147,638, D'Angelo or Stearns) in the methods of Morrison or Queen, to make the claimed antibodies. One need not independently derive monoclonal antibodies with the same specificity of the HPC-4 antibody to make the claimed antibodies.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A. Johnson, Ph.D.
Patent Examiner, Group 1806
January 30, 1998

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800